DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUN 11 2001

WARNING LETTER

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FACSIMILE
VIA FEDERAL EXPRESS

Dr. Joel Kaplan
1286 University Avenue
PMB 221
San Diego, California 92103

Re: MegaVac System (K974196)

Dear Dr. Kaplan:

The Food and Drug Administration (FDA) has reviewed various websites promoting the MegaVac System. This product is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The MegaVac System has been cleared under section 510(k) of the Act as an external penile rigidity device including vacuum pump and constriction rings. The device is intended to create and maintain penile erection in impotent men. Neither the MegaVac device nor any other legally marketed external penile rigidity devices are indicated for penis enlargement or correction of penile curvature.

The websites we reviewed include http://www.drjoelkaplan.com, http://www.kaplansvacuumpump.com, http://www.penisenlargement.net, http://www.getbiggertoday.com, http://www.impotencepump.com, http://www.surgicalpenispump.com, http://www.male-sexuality.com, and http://www.aaapenispump.com.

The websites are essentially unchanged from the website we initially reviewed in August 2000 (http://www.drjoelkaplan.com), containing the same unacceptable claims for penis enlargement and/or correction of penis curvature.

We had previously discussed your "Frequently Asked Questions" section, at http://www.drjoelkaplan.com/allfaqs.html, Question #16, that asks "Is the pump safe?" The answer given is "There are virtually no side effects." We indicated in our August 18, 2000, letter to you that we believed a more acceptable response would be "Side effects are infrequent and minor, and can be minimized by not misusing the device." We have also previously noted that indicating that your device is "FDA Approved" is not accurate, as the device was cleared through a 510(k) and found substantially equivalent; the word "approved" should be used only with a PMA product. Additionally, the statements continue to associate the FDA approval with off-label uses for penis enlargement or correction/reversal of penis curvature and penis shrinkage.

The websites have had a new link activated, entitled "Resolve Impotence," which takes the reader to the Urology Channel's website discussion of erectile dysfunction at http://www.drjoelkaplan.com/impotence.html. This webpage link is acceptable, as claims of treatment for erectile dysfunction/impotence (and premature ejaculation) are typical for vacuum erection systems and are consistent with the indications for use of the MegaVac. However, the header on this page indicates "Dr. Joel Kaplan's Penis Enlargement Vacuum Pump Systems."

We have previously corresponded directly with you on August 18, 2000 and September 28, 2000, and with your representative, Krista Nielsen, on November 27, 2000 and February 12, 2001. You were sent copies of the correspondence with Ms. Nielsen. In our previous letters, we have gone into substantial detail to answer your questions and explain how your device was cleared, what the device was and was not cleared

for, and how it may be promoted. We have advised you of what is objectionable on your website. We have advised you of the premarket notification processes and the intended uses of External Penile Rigidity Devices. We have provided you with FDA contacts regarding submission of a 510(k) and for further regulatory assistance.

The MegaVac System is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The MegaVac System is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your MegaVac System. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office, 19900 MacArthur Blvd., Suite 300, Irvine, California 92612-2445.

Sincerely yours,

Deborah A. Wolf

for

Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health